

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Commander's Policy on Human Research Requiring Institutional Approval – 02-13

1. REFERENCE AR 40-38, Clinical Investigation Program.
2. Clinical Investigation is defined broadly in AR 40-38 as organized inquiry into clinical health problems for all conditions that are of concern in providing health care to the beneficiaries of the military health care system including active duty personnel, dependents and retired personnel. This includes research involving the collection or study of existing data, documents, records and pathological or diagnostic specimens.
3. The following clinical investigations require review and approval by the Research Review Service of the Department of Clinical Investigation (DCI) and, if required by regulation, by the Clinical Investigation Committee (CIC) and/or the Human Use Committee/Institutional Review Board (HUC/IRB).
  - (a) The collection or study of existing data, documents or clinical records. This includes chart reviews and other similar uses of existing materials. In most cases, these studies do not require additional patient consent.
  - (b) The prospective collection or study of data, documents and records derived from routine patient care which involves ten (10) or more patients. These studies may require informed consent from patients.
  - (c) All collections or studies of pathologic or diagnostic specimens of any human tissue or body fluid. These investigations must also be approved by the Chief, Department of Pathology and Area Laboratory Services or the Medical Director of the appropriate Commander's laboratory.
  - (d) Studies involving more subject participation than required for routine patient care. These studies will require informed consent from subjects.
  - (e) Use of investigational drugs or devices for patient care or research. These studies will require informed consent from subjects.

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SUBJECT: Commander's Policy on Human Research Requiring Institutional Approval - 91-03

4. Questions regarding human research requiring institutional approval may be referred to the Department of Clinical Investigation at (202) 782-6389.

MICHAEL A. DUNN  
COL(P), MC  
Commanding

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